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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/619,992	07/15/2003	Steven Hefeneider	00-617-F	8235

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EXAMINER

LI, RUIXIANG

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 08/31/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/619,992

Applicant(s)

HEFENEIDER ET AL.

Examiner

Ruixiang Li

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07/15/2003 and 11/03/2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Status of Application, Amendments, and/or Claims

1. Applicants' preliminary amendment filed on 07/15/2003 has been entered. Claims 1-6 are pending and under consideration.

Objections to the Title

2. The title of the application is objected. The following title is suggested: "Mammalian cell surface DNA receptor".

Drawings

3. The drawings filed on 07/15/2003 and 11/03/2003 are accepted by the Examiner.

Claim Rejections—35 USC § 112, 1st paragraph

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a human cell surface DNA receptor (DNA-R) set forth in SEQ ID NO: 2, a DNA binding fragment comprising amino acids 1-575 of the amino acid sequence of SEQ ID NO: 2, or a soluble human DNA-R with the amino acids 1133-1171 of SEQ ID NO: 2 are deleted, does not reasonably provide

enablement for their derivatives. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The factors that are considered when determining whether a disclosure satisfies enablement requirement include: (i) the quantity of experimentation necessary; (ii) the amount of direction or guidance presented; (iii) the existence of working examples; (iv) the nature of the invention; (v) the state of the prior art; (vi) the relative skill of those in the art; (vii) the predictability or unpredictability of the art; and (viii) the breadth of the claims. *Ex Parte Forman*, 230 USPQ 546 (Bd Pat. App. & Int. 1986); *In re Wands*, 858 F. 2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988).

The breadth of the claims. The claims recite not only a human cell surface DNA receptor (DNA-R) set forth in SEQ ID NO: 2, a DNA binding fragment comprising amino acids 1-575 of the amino acid sequence of SEQ ID NO: 2, or a soluble human DNA-R with the amino acids 1133-1171 of SEQ ID NO: 2 are deleted, but also recite their derivatives. Thus, the claims are broad and encompass any derivatives of the cell surface DNA receptor set forth in SEQ ID NO: 2 since there is no structural and functional limitations for these derivatives.

Nature of the invention and the state of the prior art. The instantly claimed invention is related cell surface DNA receptors. Existence of a cell surface DNA-binding receptor had been speculated for over a decade before the discovery of a human gene coding for a membrane-associated nucleic acid-binding protein (Siess, et al. *J. Biol. Chem.* 275:33655-33662, 2000). Among the early literature related to

DNA-R, Hefeneider et al. identified a cell surface DNA receptor by binding assays (*J. Invest. Dermatol.* 94:79S-84S, 1990). However, the cell surface DNA receptor has only recently be characterized at the molecular level due to the nature of complexity of the research. Up to now, only one cell surface DNA receptor has been cloned, and the amino acid sequence and the nucleic acid sequence encoding the receptor determined.

The amount of direction or guidance presented and the existence of working examples. Despite the fact that the instant disclosure provides sufficient guidance on how to make and use a human cell surface DNA-binding receptor of SEQ ID NO:2, a DNA binding fragment comprising amino acids 1-575 of the amino acid sequence of SEQ ID NO: 2, or a soluble human DNA-R, the instant disclosure fails to provide sufficient direction or working example on how to make or use their derivatives. The specification provides general guidance regarding how to make and test variants, but provides no guidance specific to the disclosed receptor of SEQ ID NO: 2. For example, the specification is silent with respect to which amino acid residues or regions are critical for ligand binding, signal transduction, etc., and which residues may be altered without loss of activity.

The relative skill of those in the art, the predictability or unpredictability of the art, and the quantity of experimentation necessary. Although one skilled in the art certainly has the technology and skills to clone a specific gene, the fact that only one cell surface DNA binding receptor has been cloned up to now indicates the complexity of the work in this research area. The information available in the art and

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disclosed in the instant specification, while useful to a certain degree, would not be sufficient to predict whether a given derivative will have the same biological functions as that of the cell surface DNA-R of SEQ ID NO: 2. Without sufficient guidance to make and use derivatives of DNA-R of SEQ ID NO: 2, it would take undue experimentation for one skilled in the art to make and use the instantly claimed genus of derivatives.

Accordingly, while being enabling for a human cell surface DNA receptor (DNA-R) set forth in SEQ ID NO: 2, a DNA binding fragment comprising amino acids 1-575 of the amino acid sequence of SEQ ID NO: 2, or a soluble human DNA-R with the amino acids 1133-1171 of SEQ ID NO: 2 are deleted, the specification fails to enable the genus of derivatives of cell surface DNA receptor of SEQ ID NO: 2. It would require undue experimentation for one skilled in the art make and use the invention commensurate in scope with these claims.

Claim Rejections—35 USC § 112, 2nd paragraph

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-6 are indefinite because the claims recite "having a molecular weight of about 150 (63, or 145) kilodaltons". However, it is unclear whether it is referred to

a calculated molecular weight or a determined molecular weight and what method is used to determine the molecular weight if referred molecular weight is experimentally determined. Since the method by which the molecular weight is determined greatly affects the value obtained, the recitation of a value without reference to the method is meaningless, rendering the claims indefinite.

Moreover, it is unclear whether the recited limitation, "having a molecular weight ..." in each claim, limits DNA-R or its derivatives, rendering the claim indefinite. It is also suggested that the claims be amended to provide the complete name for DNA-R, such as "a mammalian cell surface DNA receptor (DNA-R)".

Claim Rejections—35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claim 4 is rejected under 35 U.S.C. 102(b) as being anticipated by Fantin et al. (*J. Biol. Chem.* 273:10726-10732, 1998).

Fantin et al. teach a membrane preparation from human embryonic kidney 293 cells (page 10727, 2nd paragraph of left column; Fig. 1), which express the claimed cell surface DNA receptor (See Fig. 5 of the instant disclosure). Thus, the membrane preparation of 293 cells taught by Fantin et al. contain naturally the claimed DNA receptor, meeting the limitations of claim 4.

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10. Claim 4 is rejected under 35 U.S.C. 102(b) as being anticipated by Hefeneider et al. (*J. Invest. Dermatol.* 94:79S-84S, 1990).

Hefeneider et al. teach a cell surface DNA receptor which are expressed in human peripheral blood mononuclear cells (PBMC). Hefeneider et al. further teach a membrane preparation from human PBMC which contain a cell surface DNA receptor (see, e.g., Abstract; page 80S, 3rd paragraph of right column), which is likely the same receptor as the instantly claimed. It should be noted that the limitation of "having a molecular weight of about 150 kilodaltons" does not really limit the claimed DNA-R, because there is no indication on how the molecular weight is determined or whether the molecular weight is referred to a calculated molecular weight or an experimentally estimated molecular weight. Even if the cell surface receptor taught by Hefeneider et al. is different from the instantly claimed receptor, the claimed DNA receptor exists, in nature, in the membrane of PBMC. Thus, the reference of Hefeneider et al. meets the limitations of Claim 4.

Conclusion

11. No claims are allowed.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (571) 272-0875. The examiner can normally be reached on Monday through Friday from 8:30 am to 5:00

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pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (571) 272-0829. The fax number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, please contact the Electronic Business Center (EBC) at the toll-free phone number 866-217-9197.



Ruixiang Li, Ph.D.
Primary Examiner
August 28, 2005